DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 13, 2015

Danville Materials, LLC
Ms. Dong Hua
Regulatory Affair Director and QA Manager
3420 Fostoria Way, Suite A-200
San Ramon, CA 94583

Re: K142881
Trade/Device Name: DMRC Dual Cure Orthodontic Band Cement
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: January 13, 2015
Received: January 15, 2015

Dear Ms. Hua:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142881

Device Name

DMRC Dual Cure Orthodontic Band Cement

Indications for Use *(Describe)*

DMRC Dual Cure Orthodontic Band Cement is a dual-cure adhesive intended for use as an orthodontic band cement for bonding of orthodontic bands to enamel

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(K) Summary

This summary of the Traditional 510(K) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807.92

A. **Applicant's Name and Address**

- Name: Danville Materials LLC
- Address: 3420 Fostoria Way Suite A-200
  San Roman, CA 94583
  USA
- Contact Person: Dong Hua
- Title: Regulatory Affair Director and QA Manager
- Phone: 800-827-7940/925-973-0710. Ext. 212
- Fax: 925-973-0764
- Date Summary Prepared: January 13, 2015

B. **The Name of the Device**:

- Trade/Proprietary Name: DMRC Dual Cure Orthodontic Band Cement
- The common name of the device: Dental adhesive, bracket and tooth conditioner, Resin
- The Classification Name: Bracket adhesive resin and tooth conditioner per 21 CFR 872.3750, product Code DYH has been classified under section 513 of the Act as a Class II device

C. **Legally Marketed Predicate Device to Which Substantial Equivalence (SE) is claimed:**

- **K073697** Transbond Supreme Adhesive By 3M Unitek

D. **Description of the Device**:

DMRC Dual Cure Orthodontic Band Cement is a resin based material containing a dual-cure adhesive for cementation of orthodontic bands. The DMRC Dual Cure Orthodontic Band Cement is a polymer based filling and restorative material; it contains a base and catalyst for dual curing process as orthodontic band cement. This product can be used for patients of all ages. The materials used in DMRC Dual Cure Orthodontic Band Cement are the same as used by our predicates, Transbond Supreme Adhesive By 3M Unitek (K073697), which is the similar dental adhesive Product. The raw chemical materials have been widely used by numerous manufacturers in the medical/dental industry.

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- Indication For Use: The DMRC Dual Cure Orthodontic Band Cement is a dual-cure adhesive intended for use as an orthodontic band cement for bonding of orthodontic bands to enamel.

E. A comparison **of the Transbond Adhesive Products by 3M Unitek** and **the DMRC Dual Cure Orthodontic Band Cement** to determine **SE**:

- The equivalence to the predicate device is supported by the physical performance testing
- Chemicals, function of each component of the product are identified
- Similarities in the Indications for Use:

Product	510(K) Number	Classification Name	Indications For Use
3M Unitek's Transbond Supreme Adhesive	K073697	Bracket Adhesive Resin and Tooth Conditioner	Light cure orthodontic adhesive designed for bonding brackets and other bondable appliances to etched enamel
DMRC Dual Cure Orthodontic Band Cement	K142881	Bracket Adhesive Resin and Tooth Conditioner	A dual-cure adhesive intended for use as an orthodontic band cement for bonding of orthodontic bands to enamel

- Discussion of Non-Clinical and Clinical Tests performed for Determination of Substantial Equivalence:

DMRC Dual Cure Orthodontic Band Cement is a resin based material containing a dual-cure adhesive for cementation of orthodontic bands. The materials used in DMRC Dual Cure Orthodontic Band Cement are the same as used by our predicate, Transbond Supreme Adhesive By 3M Unitek (K073697), which is a similar dental adhesive product. The raw chemical materials have been widely used by numerous manufacturers in the medical/dental industry.

Non-Clinical Testing performed on DMRC Dual Cure Orthodontic Band Cement included the following:

- Vickers Hardness
- Ultradent Bracket Shear Bond Strength
- Work and Set times for Orthodontic Products
- ISO 10993 testing for Cytotoxicity

All testing performed on the DMRC Dual Cure Orthodontic Band Cement was derived from the risk assessment which evaluated the effects of the feature changes. The efficacy or suitability to the intended purpose of DMRC Dual Cure Orthodontic Band

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Cement has been demonstrated by a combination of in-house testing and side-by-side comparisons to the predicate device currently on the market. Results of our bench testing indicate that DMRC Dual Cure Orthodontic Band Cement performs as well as the predicate device currently on the market.

Discussion of Clinical Tests performed:N/A

F. **Conclusion**:

Our records indicate that our predicates have been used by dentists and large group practices in the United States and purchased by a large number of international distributors.

In conclusion, the subject device, DMRC Dual Cure Orthodontic Band Cement has been designed and manufactured with the intended use and claims for the product in mind. The bench testing contained in our submission demonstrates that there are no differences in their technological characteristics, thereby not raising any new issues of safety or effectiveness. The DMRC Dual Cure Orthodontic Band Cement is as safe and effective as the predicate device, and may be released to the market.